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In the Drawings:

Kindly accept and enter the attached replacement drawing sheets amending Figures 1, 7, 8, 9, 13, 16, and 18.

REMARKS

The Applicant appreciates the thorough review of the Application by the Examiner and the interview courteously granted by the Examiner and the Examiner's SPE to Applicant's Counsel Clifford D. Hyra. Reconsideration and allowance of all claims as amended is respectfully requested.

By this Amendment, the drawings have been amended to more clearly show how the various figures relate. For example, Figure 9 shows that the elements of the lever arm arrangements for transferring movement to a dose-counting mechanism begin at one end of the lever 8. Therefore these elements would be located in region A of Figure 1 as indicated. Figure 8 shows a secondary lever connected to the canister and a means for translating its movement to a dose-counting mechanism. These elements would therefore be connected to the bottom of the canister in region B as shown in Figure 1 as amended. The wheel 30 is found in both Figure 7 and Figure 9, although Figure 9 does not show the remainder of the dose-counting mechanism. To show how these figures relate, region C has been indicated in each figure.

Figures 8, 9, 13, and 16 have also been amended to illustrate that the dose counting mechanism is inside the housing. Figure 18 has been amended to show the means 44 for translating the motion of the secondary lever arm to a dose-counting mechanism ("secondary lever 80... will create input for the dose counting device... the input movement from the lever 77 can be transformed to any desired input via the secondary lever 80." Page 30, last paragraph, "translation of the downward movement by the means here schematically indicated as a box 44 will translate this movement into a movement of the [dose counting mechanism]." Page 28, lines 24-32). Region B is indicated to relate Figure 18 to Figure 8, which illustrates how the translating means 44

may interact with the dose-counting mechanism. The Specification has been amended in accordance with the drawing changes.

The drawings are not intended to limit the possible dose-counting mechanisms that can be used with each embodiment. The dose-counting mechanisms are generally interchangeable with minor mechanical modification. The figures as amended merely make clear how the primary device may be related to the dose-counting mechanism. One main improvement of the present invention is merely the fact that movement is translated from the lever arm or canister to another element, which allows linear or non-linear translation and a more reliable indication of doses administered.

Claims 1 - 16 have been amended for clarity and to overcome the claim objections. Claim 4 has been rewritten in independent form. Claim 3 has been amended to clarify that the cap does not abut the canister or canister engagement means in its open position, allowing the lever to move the canister. This stems from the separate cap and lever construction of the present invention and distinguishes from Bruna, which has a combined cap and lever and requires a complex system to sense inhalation before dispensation. Claims 1 - 16 remain pending in the Application. No new matter has been added by the amendment. No new issues are raised by the amendment.

Regarding the 35 U.S.C. 112, first paragraph rejection, non-linear transfer of movement (by itself) is enabled by the Specification. Kindly note that transfer of non-linear movement is not what is required by the claim. Rather, a non-linear transfer of movement is taught. This is enabled by the Specification. See Figures 17 - 18 and Page 15, line 30 - Page 16, line 24 ("the pivotably fastened lever arm has an engagement point which engages a translating yoke, which yoke comprises a projecting member... where the engagement point engages the yoke on an upper surface of said yoke... In an alternative embodiment of the engagement point/yoke the upper

surface of the yoke is divided into two or more distinct linear sections, where the lever arms engagement points' travel along the second section creates a substantial part of the yoke's downward movement..." In the embodiment of Figures 17 and 18, the lever 77 and its pin 78 rotate in a circular motion. Due to the varying slope of the top surface of the yoke 79, downward movement of the lever is translated in a non-linear fashion into downward movement of the yoke. A constant downward movement of the lever does not result in constant downward movement of the yoke. Rather, the yoke may move downwards little at first for a large movement in the lever, and then move a large amount for a small movement of the lever. Thus, the movement is translated in a non-linear fashion.

TELEPHONIC INTERVIEW RECORD

Applicant appreciates the interview courteously granted by the Examiner and his SPE to Applicant's Counsel Clifford D. Hyra on June 25, 2008. The parties discussed the drawing objections. The parties agreed that the relationship between the drawings should be made clearer, with indications of where the elements of one figure would be relative to those of another.

Claims 3 and 6 are patentable under 35 U.S.C. 102(b) over Bruna et al. (5,692,492).

For an invention to be anticipated, it must be demonstrated that each and every element of the claimed invention is present in the "four corners" of a single prior art, either expressly described therein or under the principle of inherency. Lewmar Marine Inc. v Barient Inc., 3 USPQ2d 1766, 1767-1768 (Fed. Cir. 1987) (emphasis added). The absence from a prior art reference of any claimed element negates anticipation. Kloster Speedsteel AB v. Crucible, Inc., 230 USPQ 81, 84 (Fed. Cir. 1986).

Claim 3 as amended distinguishes from Bruna at least in that it teaches that the cap no longer abuts the top of the pressurized canister or the means for engagement with the bottom end of the pressurized canister when the cap is in its open position. This is a result of the very different construction of the present invention from Bruna.

Claim 6 depends from and shares the patentable features of Claim 3 and adds a lever arm that is flush with or contained in the housing when the cap is closed and projects from the housing when the cap is opened. In claim 6, the Examiner interprets the cap 6 (see fig 1-4) as a section of the housing. It is however clear, especially from fig. 1 and 4 that the housing (which encloses the canister) is not integral or part of the cap, but the cap is an "extra" part of the housing. It is therefore believed that the interpretation by the Examiner is improper. From Fig. 7 and 8 this becomes even more evident. The "lever arm" of Bruna always extends from the housing, whether the cap/lever is open or closed.

For at least the above reasons, the rejection of Claims 3 and 6 under 35 U.S.C. 102(b) over Bruna is improper and should be withdrawn.

Claims 3 and 4 are patentable under 35 U.S.C. 102(b) over Bacon (5,447,150).

Relating to the Bacon reference, it is believed that the correct reference no. is US 5,447,150. Claim 3 is distinguished from Bacon at least in that the lever arm 540 of Bacon does not engage the canister 25, but the guiding means 420. No seat is provided for engagement with the canister 25. Cap 510 does not abut the top of the canister 25. The referenced means 530 is a yoke engaging the guiding means 420 engaged at the bottom of the canister.

Therefore Bacon does not anticipate Claim 3. Claim 4 also teaches the elements of Claim 3 and is therefore for at least that reason is also novel and nonobvious.

For at least the above reasons, the rejection of Claims 3 and 4 under 35 U.S.C. 102(b) over Bruna is improper and should be withdrawn.

Claims 1 - 3, 6 - 8, and 10 - 13 are patentable under 35 U.S.C. 103(a) over Bruna (5,692,492) in view of Rand et al. (6,260,739).

The examiner combines Bruna and Rand (US 6,360,739). "To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (emphasis added).

Firstly, Bruna differs from the present invention as defined in claim 3, as already explained above. Furthermore the dose counting mechanism according to Rand, does not utilise a yoke, so even if the skilled person would modify the Bruna device and combine with the teachings from Rand, a device including a dose counting mechanism would result. It is known in

the art to incorporate dose counting devices in these types of devices. The present invention, due to its inventive construction, utilising a yoke, and the manner in which it is integrated into the housing, provides a device which is different from the suggested devices or even the comparable components of the suggested devices, such that it is not realistic that the proposed device would be anticipated by combining the available prior art.

The Examiner allows that Bruna does not teach or suggest yoke means for transferring movement to a dose counting mechanism arranged in the housing as claimed in Claims 1 - 2, 6 - 8, and 10 - 13. Furthermore, the Examiner does not argue that Rand supplies this yoke means that is lacking in Bruna. In fact, it does not. The yoke means, for example of Figures 17 and 18, is quite unique and unlike anything in the references. The Examiner also does not argue that Rand supplies the elements of Claim 3 that are missing from Bruna. Bruna and Rand, taken alone or in combination, do not teach or suggest each and every claim limitation. Dependent claims 2, 6 - 8, and 10 - 13 depend from independent and patentable Claims 1 and 3 and add further patentable limitations.

For at least the above reasons, the rejection of Claims 1 - 3, 6 - 8, and 10 - 13 under 35 U.S.C. 103(a) over Bruna in view of Rand is improper and should be withdrawn.

Claims 1 - 5 and 8 - 9 are patentable under 35 U.S.C. 103(a) over Bacon (5,447,150) in view of O'Leary (2002/0073996).

Bacon is distinguished from Claim 3 as explained above. In the Bacon reference when the Examiner combines with the teachings of O'Leary (US 2002/0073996), the Examiner interprets the vane 550 as a lever arm. The mechanism according to Bacon is clearly described in detail in col. 7, l. 7 through col. 8, l. 28. The vane is operated or more correctly activated by a

certain air speed past the vane, which air speed moves the vane. The vane is biased such that a desired air speed may be decided.

Furthermore there is no mechanical contact between the vane/lever arm 550 and the yoke/camfollower 530, whereby it is clear that the functionality provided by the present invention will not be obtained by the Bacon device.

By further combining with O'Leary does not provided the missing features, and since neither Bacon nor O'Leary addresses the problem to which the present invention provides a solution, the skilled person would not recognise a solution comparable to the present invention by combining the teachings from Bacon and O'Leary.

The dose counting mechanism according to O'Leary is described in [53] – [57], and comprises two bobbins, along with a number of discs, springs etc. The dose counting mechanism is activated once the cap of the device is replaced over the mouthpiece, assuming that a dose has been dispensed. With the present invention the dose counter is activated during dispensation. Furthermore, the dose counting mechanism according to O'Leary operates with two yokes and a ratchet mechanism in order to carry out its function. These features are also not present with the present invention, which has been kept simple, utilising one activating yoke.

Claim 1 requires that transfer of movement from the lever arm due to activation of said lever arm to the yoke is linear and/or non-linear, and that the yoke comprises means for transferring the movement to a dose counting mechanism arranged in the housing. Bacon and O'Leary do not teach or suggest this element. O'Leary teaches yokes for its dose counting mechanism, but they do not transfer movement from a lever arm activated by a user to dispense a dose to the dose counting mechanism. O'Leary counts doses based on movement of the cap and

not of a lever that activates to dispense a dose. Nothing in either of the references, taken alone or in combination, teaches or suggests anything similar to what is taught by Claim 1.

For at least the above reasons, the rejection of Claims 1 - 5 and 8 - 9 under 35 U.S.C. 103(a) over Bacon in view of O'Leary is improper and should be withdrawn.

Claims 1 and 14 - 16 are patentable under 35 U.S.C. 103(a) over Bacon (5,447,150) in view of O'Leary (2002/0073996) and further in view of Christup et al. (2001/0025639).

Bacon and O'Leary, as explained above, do not teach or suggest each and every element of Claim 1. Christup does nothing to add what these references are lacking, nor does the Examiner argue otherwise.

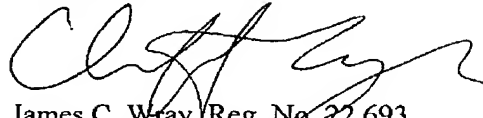
Claims 14 - 16 depend from and share the patentable limitations of Claim 1 and add further patentable limitations. In addition, Christup does not appear to be compatible with Bacon. The combination of the three references Bacon, O'Leary and one of the inventors of the present invention's earlier applications, appears unrealistic due to the divergences of the prior art documents listed above, and the fact that a third source (Christup) is necessary in order to introduce missing features. This objection appears to be created in hindsight, which privilege the skilled person does not have.

For at least the above reasons, the rejection of Claims 1 and 14 - 16 under 35 U.S.C. 103(a) over Bacon in view of O'Leary and further in view of Christup is improper and should be withdrawn.

CONCLUSION

Reconsideration and allowance of all claims are respectfully requested.

Respectfully,



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